

Part 2 – Remarks

Further consideration of the patentability of pending claims 1-40 and 44-48 is respectfully requested in view of the telephone interview conducted on June 3, 2008 and the Amendment and Response to First Office Action filed April 28, 2008.

Claim Amendments

Claim 34 has been amended by incorporating subject matter from dependent claims 41-43. That incorporated subject matter relates to a coiled section of the inflation tube which winds around the insertion tool.

As a consequence of this amendment to claim 34, the dependency of claims 44, 45, 47 and 48 has been changed to refer to amended claim 34.

No new matter has been introduced by these amendments.

Interview Summary and Comments regarding Patentability

During the interview of June 3, the undersigned essentially advanced the same arguments for patentability as were expressed in the April 28 Amendment and Response. The Examiners elaborated on the basis for the original obviousness rejection stated in the October 29, 2007 Office Action, based on Rioux (US patent 6,494,855) in view of Gellman (US patent application 2004/0078088).

It is respectfully requested that the Examiners reconsider the remarks of the April 28 Amendment and Response, in addition to the following comments. The following comments summarize the arguments for patentability presented during the interview.

A. Claim 1

As more specifically recited in independent claim 1, an inflation tube extends from a main body of an indwelling prostate-type catheter through the orifice of the external urinary sphincter muscle and along the urinary canal in the penis. The inflation tube delivers fluid to expand the balloon. A coiled section of the inflation tube proximal (downstream) of the sphincter muscle acts as a restraint or anchor to prevent the main body of the catheter from moving distally (upstream) into the bladder.

Using a coiled section of an inflation tube as a restraint against upstream movement into the bladder is not disclosed or suggested by Rioux or Gellman. While both Rioux and Gellman use restraints, neither uses a portion of the inflation tube for

that restraint. Rioux uses an entirely separate catheter tube segment 20 as the restraint, and uses the separate inflation tube only for inflation. Gellman has no inflation tube. Rioux fails to recognize or suggest the use of the inflation tube for the additional benefit of the restraint. Neither Rioux nor Gellman uses an inflation tube for two purposes, inflation and restraint. Neither Rioux nor Gellman teaches or suggests combining two separate, previously-performed functions (restraint and inflation) so as to be achieved by a single component, the coiled section of inflation tube.

The Examiners pointed out that Gellman showed a coiled configuration as an restraint. However, as was pointed out in response, combining Gellman with Rioux results in the substitution of Gellman's coiled restraint for Rioux's tube segment 20 restraint, and the result of that substitution does not involve Rioux's inflation tube. The combination of Rioux and Gellman, as proposed by the Examiners, simply does not teach, recognize or suggest that the inflation tube may be used for a restraint.

Rioux and Gellman simply fail to teach, recognize or suggest the beneficial improvement of claim 1 of integrating the restraint function with the inflation function in the inflation tube. Nothing about the proposed combination of Rioux and Gellman addresses or suggests the fact that the inflation tube can be used as a replacement for the separate downstream restraint. The failure of the proposed combination of Rioux and Gellman to reach the scope and improvement of claim 1 demonstrates the nonobviousness of claim 1 and the other pending claims.

B. Claim 34

Amended claim 34, as well as claims 10-19, 20-23 and 43-47, are directed to a combination of a catheter with an insertion tool, in which a coiled section of the inflation tube forming the upstream restraint is coiled around the insertion tool when the tool and the catheter are connected.

Independent claim 34 additionally recites, in the manner set forth, a separable connection between the main bodies of the catheter and the insertion tool. The separable connection allows the catheter and the insertion tool to be moved as a unit when inserting the catheter. The separable connection also allows selective separation of the catheter and the insertion tool in response to proximal movement of the insertion

tool when the expanded balloon restrains the catheter main body against proximal movement from the use position. This recited separable connection feature is not disclosed or suggested by Rioux and Gellman.

The insertion tool described in Gellman is completely different. Gellman's insertion tool connects to the opposite ends of his coiled stent and twists one end of the stent relative to the other to constrict the coils of stent tightly around the insertion tool. The stent is inserted in this tightly coiled configuration, and once inserted, the ends of the stent are disconnected from the insertion tool to allow the resiliency of the coils to unwind and expand the stent in place.

Releasing the opposite ends of tightly coiled spring-like stent is not related to separating an end-to-end connection by restraining the catheter with the expanded upstream balloon while pulling the insertion tool downstream. The issue of how or why the Gellman insertion tool, which relies on rotary motion to constrict the diameter of a coiled device, could or would be combined with the Rioux device which appears to be incapable of constricting diametrically or even to receive an insertion tool as described in Gellman, was not explained by the Examiners during the interview, except that the Examiners took the position that the separable connection was broadly recited.

It was briefly noted during the interview that nothing in Rioux or Gellman discusses or suggests how the insertion tool should interact with the coiled section of the inflation tube. Accordingly, to even further distinguish claim 34 from Rioux and Gellman, claim 34 has been amended to include the coiled section of the inflation tube, which is coiled around the insertion tool when the catheter and the insertion tool are connected.

The lack of similarity in structure, function or relationship between the characteristics of the the pending claims and the combination of Rioux and Gellman, and even the fact that if Rioux and Gellman were combined, that combination would still not reach the scope of the pending claims, demonstrates that the catheter and the insertion tool combination claim should be patentable.

Conclusion

As a result of the amendments and remarks set forth above, it is believed that all pending claims define patentable subject matter and are in condition for allowance. Allowance is respectfully requested. The Examiner is requested to contact the undersigned by telephone to discuss any issues which may inhibit the immediate allowance of the claims.

Any fees associated with this Amendment and Response may be charged to Deposit Account 12-1087.

Respectfully submitted,

June 13, 2008

/John R. Ley/

Registration No. 27,453  
ATTORNEY FOR APPLICANT

Customer No. 28785

JOHN R. LEY, LLC  
5299 DTC Boulevard, Suite 610  
Greenwood Village, Colorado 80111-3327  
Telephone: (303) 740-9000  
Facsimile: (303) 740-9042